AMERICAN CHEMISTRY COUNCIL COMMENTS ON THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S TSCA §6(a) PROPOSED REGULATION OF CERTAIN USES OF TRICHLOROETHYLENE

Docket No. EPA-HQ-OPPT-2016-0163

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EXECUTIVE SUMMARY

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA or the Agency) on its proposed risk management measures under section 6 of the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) for certain commercial and consumer uses of trichloroethylene (TCE).[2] ACC submits these comments in response to EPA's December 16, 2016 proposal to prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities.[3] Additionally, ACC supports the comments of ACC's Chemical Products and Technology Division submitted on this proposal and filed separately in the docket.

EPA takes this action pursuant to TSCA section 6(a), which requires the Agency to apply one or more control requirements "to the extent necessary" to reduce the risk posed by a chemical which has been found through a risk evaluation to present an unreasonable risk of injury to health or the environment. [4] These requirements can include any combination of restrictions, limitations on presence, or outright prohibitions on specific uses (e.g., manufacture, processing, distribution, etc.) of the chemical substance in question. These may be selected in conjunction with other requirements for recordkeeping, labeling, or notification for manufacturers or processors of these substances. Despite its selection of a prohibition on aerosol degreasing and spot cleaning uses, the proposal's cursory analysis of alternative regulatory options fails to meet EPA's burden to demonstrate that these other options (or a combination of them) would not satisfy its goal to eliminate the relevant unreasonable risks.

ACC provides these comments to assist the Agency in its broader development of a chemical evaluation and management program under the LCSA amendments to TSCA that is efficient, science-based, and consistent with the legal requirements of TSCA.

While ACC member companies are not engaged in the manufacturing or processing of TCE for uses covered by the proposed rule, we have the following concerns given the proposal's precedential nature as EPA's first section 6 risk management decision under TSCA as amended by the LCSA:

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[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

[2] Public Law 114-182 (June 22, 2016). References to TSCA in these comments are to TSCA as amended by the LCSA unless otherwise indicated.

[3] 81 Fed. Reg. 91592.

[4] 15 U.S.C. 2605(a).

- EPA's proposal must clearly comport with TSCA Sections 6 and 26 requirements, which include a risk management decision consistent with the scope of the prior completed risk assessment and a requirement that all decisions be based on the best available science, among others.
- The cost and benefit analysis that supports the rulemaking does not satisfy key regulatory guidelines and best practices such as those detailed in OMB Circular A-4. EPA must ensure that the proposed rulemaking satisfies the statutory mandate that EPA apply the best available science and the weight-of-the-scientific evidence. Further, EPA should not simply extrapolate data from other sources and apply it to the applicable sectors without careful review.
- Risk management measures applied in response to a TSCA risk evaluation should be based on consideration of a comprehensive set of factors. These measures should not be based on a cursory evaluation of the effectiveness of any one risk management measure alone, but rather an evaluation of a robust set of options, including labeling, personnel training, personal protective equipment, and other useful combinations of risk management.

Comments of the American Chemistry Council on
TSCA §6(a) Proposed Regulation of Certain Uses of Trichloroethylene

I. EPA's Proposal must Comport with the Requirements of TSCA Sections 6 and 26

Scope of the Proposed Requirements and 2014 TCE Risk Assessment
As EPA notes in the proposal, TCE was listed in the 2014 update to the TSCA Work Plan for Chemical Assessments and has a completed risk assessment that was published prior to the date of enactment of the LCSA. For such chemicals, section 26(l)(4) of TSCA expressly recognizes that EPA may issue rules under TSCA section 6(a) that are "consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6" (emphasis added). As such, EPA should ensure that the requirements in this section 6(a) proposal appropriately track the scope of TCE's June 2014 risk assessment.[5] Unfortunately, EPA has chosen to use this proposal to address a broader scope of uses than considered by TCE's risk assessment. ACC is concerned that this choice not only fails to achieve consistency as required by statute, but also sets a problematic precedent for overbreadth.

In Section 1.3.1 of TCE's June 2014 risk assessment, EPA states that it included and excluded certain primary uses of TCE from further consideration based on a number of assumptions and criteria (e.g., content, frequency of use, potential for exposure, etc.).[6] EPA uses this rationale to exclude from consideration exposure from TCE's use as a solvent degreaser in large commercial/industrial settings. Instead, the risk assessment focuses solely on exposure from TCE use as a solvent degreaser in small commercial settings and by consumers.

However, this proposal's requirements extend beyond the limited scope of the risk assessment. Specifically, EPA prohibits commercial use of TCE for general aerosol degreasing, as well as its manufacture, processing, and distribution in commerce in this use. By focusing on a prohibition of commercial use in general, EPA fails to create any distinction comparable to the one EPA/OPPT made in limiting the scope of TCE's risk assessment. The risk management decision extends beyond the scope of the corresponding risk assessment and therefore lacks proper scientific support. This is particularly problematic given this proposal's precedential nature. To ensure a proper scientific foundation for all future rulemakings under this section, EPA should adhere to the statutory language laid out in TSCA Section 26(l)(4) and ensure that management decisions are "consistent with the scope of the completed risk assessment."

Best Available Science
EPA is further required to support its section 6 scientific decisions with "the best available science" as per section 26(h). This statutory mandate applies to all of EPA's scientific decisions,

[5] TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses. EPA Document# 740-R1-4002 (June 2014).
[6] Id. at 27.

regardless of the scientific discipline. It therefore encompasses not just disciplines such as toxicology, chemistry, physics, and biology, but epidemiology and exposure science, immunology, neuroscience, and cognitive and behavioral sciences. Decisions made pursuant to these and other disciplines are subject to the "best available science" standard in section 26(h).

Authorities have recognized that the application of the scientific methods extends well beyond traditional "hard" sciences. This is confirmed by scientific journals, federal agencies, and academic institutions increasingly recognizing the nature of social science disciplines as similar to that of natural sciences, and subject to comparable rigor and analysis. For example, academic institutions around the world manage graduate programs and research initiatives that utilize scientific principles to study human cognition, perception, decision making, and many associated factors that influence them.[7] Additionally, countless published scientific studies focus on the ways humans extract information through perceptual and experience-based learning, especially through warning labels.[8] Importantly, federal agencies such as the Occupational Health and Safety Administration and EPA itself have used studies like these, as well as a range of others, to inform their decisions concerning hazard perception in health and safety communication.[9]

Throughout this proposal, EPA makes assumptions about factors based in social science to inform its risk management approach. However, EPA fails to provide an adequate justification for these assumptions. EPA also fails to explain whether there is, or is not, science available in the relevant area upon which to base a decision. Where EPA does cite analyses, they appear to lack proper systematic review and robustness. For example, in section V(C) of the proposal, EPA states that it determined the lack of efficacy of labels as a risk management approach based on an analysis of studies and meta-analyses that evaluate human perception and comprehension in response to labels.[10] As discussed further in Section IV of these comments, EPA's approach did not include a systematic review and was not peer reviewed. EPA reviewed analyses that are factually disconnected from the chemical and application at hand, raising questions whether an appropriate factual nexus is present to support a conclusion. It is thus unclear whether EPA relied upon relevant science to inform its judgment; whether that science was reliable, or the best quality available. As a result, EPA reaches conclusions about human perception of, understanding of, and behavioral response to labeling that fail to meet the scientific standards of Section 26.

Further, in section VII(B)(3)(c) of the proposal, EPA makes a similar determination concerning the psychological effects of supplied-air respirators on consumers.[11] EPA assumes that the sight

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[7] George Mason University, Cognitive and Behavioral Neuroscience Concentration (http://psychology.gmu.edu/programs/la-phd-psyc-cbnr); Johns Hopkins Graduate Department of Psychological & Brian Sciences (http://pbs.jhu.edu/graduate); University of Chicago PhD Program: Behavioral Science (https://www.chicagobooth.edu/programs/phd/academics/dissertation/behavioral-science);

[8] Kellman, P. J. & Garrigan, P. B. (2009). "Perceptual learning and human expertise. Physics of Life Reviews," 6(2), 53-84; Thai, K. P., Mettler, E., & Kellman, P. J. (2011). "Basic information processing effects from perceptual learning in complex, real-world domains." In L. Carlson, C. Holscher, & T Shipley (Eds.), "Proceedings of the 33rd Annual Conference of the Cognitive Science Society" (pp. 555-560). Boston, MA: Cognitive Science Society.

[9] https://www.osha.gov/dsg/hazcom/hc2inf2.html#3.1.1.

[10] 81 Fed. Reg. 91601.

[11] 81 Fed. Reg. 91610.

of supplied-air respirators being used by workers will have a negative impact on consumer behavior. Although it provides no explanation or support for this assumption, the Agency uses it to support its decision to forego a requirement for dry cleaning facilities to use personal protective equipment (PPE). From a Section 26 standpoint, a mere assumption about how people will react under a particular circumstance could not be farther from a decision based on science. Science demands systematic study through observation and experiment, not assumption. That systematic study must either be of the specific facts at issue (e.g., the conditions of use of a substance, meaning that behavior is studied in the relevant workplace with real-work controls, training, instructions, PPE, labeling and so forth in place) or of facts and circumstances that are relevant to the issue at hand. The record fails to reflect that any such thing occurred here.

II. EPA must improve the underlying Economic Analysis that addresses the costs and benefits associated with the proposed requirements to be more comprehensive, accurate, and reflective of current industry data.

Similar to section 6(a), EPA must also adhere to the additional requirements in TSCA Section 6(c) as the Agency develops the analysis for this and future rulemakings. For example, TSCA Section 6(c)(2)(A)(iii) requires the Agency to consider "the benefits of the chemical substance or mixture for various uses."[12] Further, for any rules issued under section 6(a), TSCA section 6(c)(2)(A)(iv) requires EPA to publish a statement on the "reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health."[13] As such, to select the appropriate risk management option, EPA must accurately address the total costs and benefits associated with these proposed risk management options, as well as properly address the available substitutes for TCE that may be used after its prohibition.[14]

The reasonably ascertainable economic consequences of the rule include: the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.[15]

ACC is concerned that EPA's economic analysis supporting this proposal has significant inaccuracies and shortcomings. In its analysis, the Agency overlooks information that is reasonably available while accounting for consequences that are patently unascertainable. For instance, the impact of "personal costs (emotional, mental, and impacts to a person's quality of life)" that EPA claims "cannot be discounted" almost certainly cannot be reasonably ascertained.[16] The following areas of concern should be better addressed in the economic analysis and in subsequent section 6 rulemakings.

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[12] 15 U.S.C. 2605(c)(2)(A)(iii).
[13] 15 U.S.C. 2605(c)(2)(A)(iv).
[14] 15 U.S.C. 2605(c)(2)(C).
[15] 81 Fed. Reg. 91593.
[16] 81 Fed. Reg. 91615.

Switching Costs
EPA's Economic Analysis assumes virtually no switching costs for manufacturers or consumers, and relatively minor costs for blenders. An accurate and appropriate economic analysis would account for these costs and provide a qualitative and quantitative description of significant switching costs. EPA's lack of information on switching costs (and the use of a relatively low cost estimate for blenders "transferred" from another product substitution based on a single company experience) in the economic analysis is a weakness that could easily be improved through reasonably ascertainable information. ACC believes EPA should inquire about (1) the nature of switching costs, (2) the magnitude of switching costs, and (3) the timeframe needed to comply with the proposed rule for this and all future rulemaking analyses under section 6.

Cost-Effectiveness of Regulatory Alternatives
In this context, it appears that EPA has failed to appropriately consider the full costs of its regulatory alternatives. The Agency should improve its estimation and include an accurate consideration of each alternative's cost-effectiveness. TSCA Section 6 requires EPA to consider, when regulating an unreasonable risk, the costs and benefits of alternative regulatory actions as well as the cost-effectiveness of those alternatives considered. In the future, EPA should include a robust discussion and accurate estimation of the cost-effectiveness associated with regulatory alternatives to properly justify a selected management approach. This discussion should include an analysis of the lifecycle impacts associated with an increased use of TCE substitutes and alternatives.

Baseline TCE Use
ACC also believes that a proper economic analysis should accurately characterize baseline use of a substance, a factor laid out in OMB Circular A-4's requirement that a baseline be "the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide-range of potential factors, including evolution of the market, changes in external factors affecting expected benefits, and costs, etc."[17]

Further, "when more than one baseline is reasonable… [the Agency] should consider measuring benefits and costs against alternative baselines."[18] The development of a well-informed baseline pursuant to OMB Circular A-4's description would be a significant step toward the satisfaction of TSCA section 6's requirement for a statement that addresses the economic effects of rulemaking. EPA's economic analysis for this proposal should better characterize its baseline on TCE use over time. In this proposal, the Analysis uses a baseline based on a rough estimate of TCE use that does not change in the future in the absence of the proposed regulation. For example, trend information might show whether TCE use as an aerosol degreaser or spot remover is increasing or decreasing, which is relevant to the analysis.

Past and future regulation will affect the market for TCE. Demand for TCE could be expected to decline significantly over the next few years for reasons unrelated to this proposal, and manufacturers may not wish to produce TCE for relatively minor uses such as those uses

[17] OMB Circular A-4, *available at* https://www.whitehouse.gov/omb/circulars_a004_a-4.
[18] Id.

addressed here. The baseline should take this into account. ACC recommends that EPA use a more comprehensive baseline assessment in the economic analyses that supports this and all future section 6 rulemakings, particularly the remaining nine risk evaluations to be completed for 1,4-dioxane, 1-bromopropane, asbestos, carbon tetrachloride, hexabromocyclododecane (HBCD), methylene chloride, N-methyl-2-pyrrolidone (NMP), pigment violet 29, and tetrachloroethylene, as well as the TCE proposal for vapor degreasing.

Welfare Loss

ACC also believes that EPA's economic analysis should appropriately qualify, quantify, and monetize the welfare loss to consumers. In this economic analysis, EPA acknowledges the possibility of a welfare loss to consumers but does not explore this "possibility" any further. ACC believes that a proposed prohibition in an established market would tend to have demonstrable welfare losses which should be addressed in the economic analysis. We recommend that EPA further investigate these related consequences and more accurately account for the comprehensive impacts on consumers.

Compliance Burden and Enforcement Costs

EPA has not fully accounted for the associated enforcement and compliance burdens. For example, EPA assumed rule familiarization for SDS updates would involve one hour of time by a technically qualified individual. However, ACC members estimate that the actual time required would significantly exceed the single hour projected by the Agency. For one, EPA's SDS update assumption only accounts for the time of one qualified individual. In reality, the process for a technically qualified individual to update an SDS involves many hours of reading the rule and understanding its impacts, outside consultation with expert toxicologists, legal review, and internal clearance procedures. EPA should revise its projected compliance burden to more accurately account for these and other related impacts. ACC recommends that in the future, EPA support its section 6 economic analyses with a full explanation of why it selected certain costs and enforcement assumptions. This will be critical to accurately project the complete universe of impacts from selected management options.

Benefits of TCE Use

The economic analysis also raises concerns associated with EPA's review of the benefits of the proposed prohibition. EPA must be more specific as to the discrete benefits of TCE. In promulgating a regulation (and in selecting among regulatory restrictions), TSCA requires EPA to consider and publish a statement that includes "the benefits of the substance for its various uses" based on "reasonably ascertainable" information. EPA's analysis does not satisfy this requirement. Without this statement, the benefits of the proposal cannot be accurately estimated and the economic analysis will be further flawed. Again, ACC believes that future section 6 actions should be supported with a specific, robust, and well-founded analysis of the benefits and costs of proposed restrictions for a selected substance.

III. There are significant concerns associated with the proposal's Information Collection Request

EPA must consistently publish accurate burden estimates in Information Collection Requests. ACC is concerned that EPA has failed to do so in this proposal, and should not continue the use of these assumptions in this or future proposals. EPA should amend the final ICR to reflect improved burden estimates. ACC is concerned that the notification requirements do not focus on the TCE uses that are the subject of this proposal, and are therefore inconsistent with the Paperwork Reduction Act's mandate to "minimize burden" and "maximize practical utility" with respect to information collection. The mere possibility of utility does not equate with practical utility required of an information collection request. Importantly, EPA should only propose rules that affect the chemical-use combinations discussed in the proposal.

Notification and Recordkeeping
EPA's proposal includes a requirement that manufacturers, processors, and distributors of TCE notify in writing the companies to whom TCE is shipped about the regulatory requirements, concurrent with the shipment. The Agency should be clear as to where in the supply chain the burden (e.g., costs, time, etc.) of new notification requirements will fall, and accordingly make the necessary clarifications in the final rule. Additionally, the Agency also does not provide the specifics details (e.g. content) required to satisfy this writing requirement. While ACC supports EPA's choice to provide a range of compliance options for meeting the notification requirements, we believe it is critical that this and all other new requirements be closely tailored to the specific uses it seeks to address and properly account for associated costs and the time burden required to implement them.

Finally, EPA's determination that a particular chemical-use combination poses an unreasonable risk does not permit the Agency to regulate other uses outside the scope of that finding. This proposal seeks to impose the notification and recordkeeping requirement upon uses of TCE that extend beyond the scope of these proposed requirements or the risk evaluation on which it is based. For this and future rulemakings, EPA should not create rules affecting other chemical-use combinations not included in the scope of the rule.

IV. Selection of Risk Management Measures

EPA has asked for public comment on its analysis and process in determining whether the regulatory options considered in this proposal would address the identified unreasonable risks in aerosol degreasing and spot cleaning uses. ACC generally supports regulatory approaches that do not mandate a one-size-fits-all solution, and are sufficient to meet the statutory risk mitigation requirements as determined using the best available science and balancing the weight of the scientific evidence. In section 6 rulemakings, EPA should therefore continually utilize a number of risk management options identified as capable of mitigating risk as part of an effective suite of risk mitigation techniques. Unfortunately, EPA has not considered the full range of risk

management options as required under TSCA[19] and OMB Circular A-4,[20] and has not produced the scientifically robust analysis contemplated by Congress in passing LCSA.[21]

TSCA Section 26(h) requires that in carrying out section 6, the Agency must utilize the best available science, considering specifically whether the information used is "reasonable for and consistent with the intended use of the information," the "degree of clarity and completeness" of the "data, assumptions, methods, and analyses used," the variability and uncertainty of the information, and the extent of peer review of the information. The Agency must also base section 6 decisions on the weight of the scientific evidence.[22]

When selecting from a suite of risk management measures, EPA is required to choose those measures which would reduce the unreasonable risks identified by the Administrator such that the chemical substance in the proposal no longer presents such risks.[23] Therefore, EPA must ensure that it conducts a science-based analysis of risk management options that adequately informs the Agency of which measures will fulfill the statutory obligations. EPA should evaluate the usefulness of those measures using supporting data indicating actual practices relative to the chemical-use combination included in a proposal.

EPA should also conduct distinct analyses evaluating the effectiveness of a risk management option relative to separate user groups, such as consumers and workers. Data regarding the effectiveness of a risk management option for consumers should not be extrapolated to apply to workers as well. In performing these analyses, EPA should ensure that the data used are relevant to the populations and user groups affected by the chemical-use combination. Finally, EPA should understand the existing baseline on control measures for the options considered; further consultation with other agencies may be necessary. ACC strongly believes EPA should perform a more thorough investigation and seek a greater understanding of risk management options before proposing any particular course of action.

Labeling

ACC believes that the Agency failed to give full consideration to alternative informational approaches that may aid in risk management. EPA's proposed rule fails to adequately justify its dismissal of informational labeling measures as ineffective tools that "alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users"[24] (emphasis added). The Agency did not address the effectiveness of labeling in conjunction with other approaches. Given EPA's limited explanation (or lack thereof), a reader

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[19] 15 U.S.C. 2605, 2625

[20] OMB Circular A-4, *available at* https://www.whitehouse.gov/omb/circulars_a004_a-4

[21] Cong. Rec. S3518, June 7, 2016 Congress charged EPA to "comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

[22] 15 U.S.C. 2625(i). This term is not defined in the statute, and EPA has since declined to offer a definition or further clarity of this term. ACC understands "weight of the evidence" to mean a systematic review of scientific evidence.

[23] 15 U.S.C. 2605(a). EPA is no longer required to select the least burdensome measures.

[24] 81 Fed. Reg. 91601

may reasonably conclude that there are no circumstances under which EPA would consider informational measures or labeling, yet such measures are explicitly listed in TSCA as a regulatory control mechanism, and are utilized in other agency programs as well.[25] ACC members believe EPA should provide a more robust analysis of labeling as a risk management option in this and future rulemakings.

EPA's analysis fails to meet the TSCA scientific standards in section 26 outlined above as well as OMB Circular A-4 guidelines. Circular A-4 states the following:

> If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.[26]

In evaluating alternative regulatory approaches, Circular A-4 also states:

> [the Agency] should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation.[27]

The effectiveness of labels and warnings is a science-based determination, and therefore the Agency must adhere to section 26(h) requirements. EPA's cursory review of unspecified studies is a particular concern, particularly when EPA relies on the effectiveness of labeling in other initiatives that similarly rely on the consumer's comprehension of a label to inform consumer behavior. The Agency's position on labeling in this proposal has important consequences for private and governmental labeling initiatives.

In the supporting analysis,[28] EPA did not explain what criteria the Agency used to decide whether to include some scientific studies on the effectiveness of labeling but not others. EPA also did not discuss how the quality, relevance, and reliability of the individual studies were considered. While the Agency maintains that the meta-analysis utilized a weight of the scientific

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[25] Labeling is a critical factor in protecting workers, for instance, as determined by OSHA in its hazard communication standard, and the implementation of the Globally Harmonized System of Classification and Labeling of Chemicals.
[26] OMB Circular A-4, *available at* https://www.whitehouse.gov/omb/circulars_a004_a-4
[27] Id.
[28] Economic Analysis of Proposed Section 6 Action on Tricholoroethylene in Dry Cleaning Spot Removers and Aerosol Degreasers (November 15, 2016).

evidence approach, the specifics of the approach are not clear to readers and the analysis does not support EPA's claim that it was a weight of the scientific evidence approach.

In addition, the approach did not include a systematic review, was not peer reviewed, and did not benefit from public comment. This supplemental analysis does not appear to be of sufficient quality to support the Agency's position on labeling. EPA should include a more robust analysis of not only the labeling option, but all risk management options and also ensure that the analyses distinguish between consumer, professional, commercial, and worker circumstances of use.[29] At a minimum such an analysis should be informed by peer review and public comment.

Labeling is a logical policy response to EPA's unreasonable risk determination, and its lower cost in terms of total welfare loss compared to a prohibition makes it an attractive risk management option. The Agency's apparent position on labeling is therefore untenable. Labeling should be considered a viable risk management option in future rules; in this proposal, labeling should not be wholesale discounted without more rigorous analysis.

Personal Protective Equipment
ACC believes that EPA needs to provide a more detailed analysis for and give further consideration to personal protective equipment (PPE) as a risk management measure in this and future rulemakings. In doing so, the Agency should avoid making various assumptions about the implementation of PPE without further analysis. For example, EPA should first examine existing baseline PPE controls for the uses the agency proposes to regulate before deciding what further action is necessary to meet statutory risk reduction requirements. In order to complete this level of analysis as contemplated by Congress, the Agency should take into account, for example, all relative OSHA regulations and practices also related to the proposed chemical to be regulated. ACC believes that as part of a section 6 rulemaking, TSCA requires that EPA demonstrate and document a reasonable understanding of the nature and extent of baseline risk mitigation practices. We are concerned that EPA fails to demonstrate this understanding in the proposed rulemaking; instead EPA has made various significant assumptions regarding aerosol degreasing and spot removal uses of TCE.

EPA assumes that no users would adopt PPE since the costs of implementing a PPE program would be "prohibitively expensive."[30] However, EPA cites no evidence suggesting that in fact PPE programs would be so prohibitively expensive as to force all users to switch from one product to another. No evidence is provided showing that some businesses have already made capital investments in PPE measures which are already in place at those establishments. EPA should document the current baseline use of PPE when considering PPE as a risk management measure. In addition, the Agency assumes that workers and consumers may not actually use or understand how to use PPE.[31] The Agency does not consider that workers may receive training on respirator use and be required to wear them, or that consumer products may include use instructions and warnings alerting the user to the proper methods of product use.

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[29] Workers are required by OSHA, for instance, to have training with regard to certain labels.
[30] 81 Fed. Reg. 91617
[31] Id. at 91606

EPA finds that respiratory protection equipment[32] may "reduce exposures to levels that are protective of non-cancer and cancer risks"[33] for a chemical-use combination, but then cites an OSHA federal notice that states improperly selected respirators "may afford no protection at all, may be so uncomfortable…, and may hinder vision, communication, hearing, or movement…"[34] EPA fails to recognize that such effects are noted for *improperly selected* respirators.[35] OSHA's respiratory protection standard was meant to ensure that such improper selection would not occur, and TSCA provides EPA authority to proscribe measures ensuring that PPE selected for application in aerosol degreasing and spot cleaning uses is proper for such designated uses.

In addition, OSHA's 1998 analysis is based on nearly 20 year old technology; in 2017 respiratory technology may afford much more reliable, comfortable protection. In combination with ventilation, which alone brings exposure into the 99th percentile of meeting MOE benchmarks, a properly managed PPE program for any chemical-use combinations should be more fully considered.

Substitution Risk

ACC is significantly concerned that EPA's analysis of the available alternatives and their technical and economic feasibility falls far short of the level of transparency, clarity, and evidentiary support Congress expects in a section 6 rulemaking. With each such rulemaking, EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."[36] EPA failed to explain its process and disclose data used in evaluating the risks associated with potential alternatives. Moreover, the analysis does not meet the guidance set out in Circular A-4 that an agency's analysis should "consider any important ancillary benefits and countervailing risks," including adverse effects on the economy, health, safety, or environment of alternatives.[37] EPA should further clarify its assumptions and document the data used to support the proposal's conclusions and analyses, consistent with TSCA's principles of transparency and the best available science.

EPA's analysis is based on substantial uncertainty with regard to the hazard and exposure potential of substitutes, including hydrocarbons, mineral spirits, glycol ethers, DCM, acetone, and others. ACC does not expect EPA to conduct full risk evaluations of alternative substances. However, in the proposal and supporting economic analysis, EPA made a conclusory determination that "none of the risks" posed by any considered substitute is "expected to be

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[32] EPA notes that respiratory protection equipment would consist of "full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000." 81 FR 91605. EPA also considered the use of respirators with an APF of 1,000 in combination with ventilation measures.
[33] 81 Fed. Reg. 91605.
[34] Id.
[35] Id.
[36] 15 U.S.C. 2605(c)(2)(C).
[37] OMB Circular A-4, Ancillary benefits and Countervailing Risks, *available at* https://www.whitehouse.gov/omb/circulars_a004_a-4.

greater than the risks posed" by the chemicals in the proposed rule.[38] The Agency fails to provide support for this determination, and does not analyze hazard and exposure potential of substitutes to compare these risks to any extent. Further, the agency fails to consider lifecycle impacts of potential alternatives; an alternative chemical may deliver similar performance to the regulated chemical, but require significantly more material or energy to do so. The resulting impacts on health and the environment given a potentially significant uptick in usage of an alternative should bear on the Agency's analysis.

EPA should refrain from assigning risk to presumed chemical substitutes without an appropriate basis. In the economic analysis,[39] EPA counts certain alternatives[40] toward the quantified benefits of the proposal without accounting for risk. ACC recommends that EPA undertake a more robust and transparent risk analysis of chemical substitutes, accounting for the potential risks.

V. Coordination with other Agencies and other Section 9 Issues

ACC is concerned that EPA has made no effort to meet statutory obligations under Section 9(a), (b), and (d). Section 9(a) of TSCA requires that if the Administrator determines that an identified unreasonable risk may be prevented or reduced under another federal agency outside EPA's jurisdiction, then the Administrator must submit a report to that agency, beginning a process that may allow that agency to exercise its jurisdiction over the chemical use in the interest of public health.[41] Similarly, Section 9(b) requires that EPA "coordinate actions [under TSCA] … with actions [under other EPA statutes],"[42] and Congress added in the LCSA that an EPA decision to act under TSCA rather than another EPA statute should consider "all relevant aspects of the risk" as well as compare the relative costs and efficiencies of taking action under such laws.[43]

In addition, Section 9(d) requires the EPA to "consult and coordinate" with the Secretary of HHS, as well as any other "appropriate Federal executive department or agency…" and others in order to "achieve maximum enforcement … while imposing the least burdens of duplicative requirements." ACC is concerned that EPA has neglected each of these requirements in this proposal, and has failed to provide transparency with regard to how the Agency attempted to meet these statutory obligations.

EPA provides no explanation or evidence to show it has met Section 9(d) coordination and consulting requirements. In this proposal, EPA simply states that "[f]or today's proposed rule, EPA has consulted with CPSC and OSHA."[44] The only available evidence supporting this statement are two letters (one from each agency) to EPA regarding each agency's relative

[38] EPA Economic Analysis, Benefits, pg. 6-8; *see also* 81 Fed. Reg. 91602 "all substitutes are expected to be less hazardous than TCE."
[39] EPA Economic Analysis, Benefits, pg. 6-8.
[40] Not including PCE and 1-BP.
[41] 15 U.S.C. 2608(a)
[42] 15 U.S.C. 2608(b)
[43] 15 U.S.C. 2608(b)(2)
[44] 81 Fed. Reg. 91618

jurisdictional authority. Although these agencies' jurisdictional authority cover worker and consumer health and safety, EPA does not state how it concluded that such agencies were the only appropriate agencies, and provides no additional transparency indicating further effort to meet Section 9(a) requirements. Congress also explicitly added requirements under Section 9(b) to compare the "estimated costs and efficiencies" of acting under TSCA or another statute, but the Agency has completely failed to meet these new Section 9(b) requirements, and ignored clear Congressional directives. Compounding this problem, EPA does not address how TCE uses subject to this proposal are already covered by other EPA statutes, including the OSH Act and the Federal Hazardous Substances Act.

ACC is also concerned that EPA asserts overly broad jurisdictional authority without sufficient explanation or justification, and without regard to TSCA's gap-filling purpose or the statute's goal of avoiding duplicative requirements. To emphasize, section 9(d) implores EPA to work with other agencies and consider their ability to help reduce unreasonable risk in order to impose the "least burdens of duplicative requirements." The Agency presents no evidence of its efforts to fully meet this objective.

Congress reinforced TSCA's gap-filling nature by passing LCSA, and recognized that EPA should "respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[45] EPA should explain in greater detail how its broad assertion of authority with respect to these uses of TCE reconciles these Congressional directives. ACC believes that the Agency should more thoroughly explain how other EPA statutory authority or other federal agencies may or may not reduce an unreasonable risk that individual "activit[ies] or combination[s] of activit[ies]"[46] may present.

[45] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28. *Cf.* Detailed Analysis and Additional Views of Senators Boxer, Markey, Udall, and Merkley.
[46] 15 U.S.C. 2608(a)